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In re Patent Application of

HERSHFIELD et al.

Atty. Ref.: 1579-527

Serial No. 09/762,097

Group: 1652

Filed: August 23, 2001

Examiner: Patterson

For: URATE OXIDASE

* * * * *

Tuesday, May 28, 2002

#7
19J
6/3/02

Honorable Assistant Commissioner of Patents
Washington, DC 20231

Sir:

RESPONSE

Responsive to the Office Action dated November 27, 2001, the applicants elect, with traverse, the subject matter of the Examiner's Group V, for further prosecution in the above.

The restriction requirement should be withdrawn for any of the following reasons.

The Examiner is requested to appreciate that the present application is a 371 of PCT/US99/17678 such that the principles of unity of invention apply to this application, as opposed to restriction. See, MPEP § 1893.03(d) and Example 17 of Annex B of the PCT Administrative Instructions, copies attached. A new Office Action is requested which appropriately follows the principles of unity of invention.

The following comments relating to the Examiner's basis for the restriction requirement are included to be fully responsive, even though the Examiner's basis for requiring an election are not properly based in the present application.

The restriction requirement should be withdrawn as a search of all the claimed subject matter would not be an undue burden on the Examiner.

The restriction requirement is improper, at least with regard to, for example, Groups I-VI, Groups VII-XII and Group XIII. That is, at most, there should be three Groups of subject matter which may require restriction. Specifically, the Examiner has

admitted that a search of, for example, Groups I-VI would require a search of the exact same class and sub-class within the Patent Office classification system. Clearly, this subject matter has not attained a separate status in the art as defining separately patentable inventions. Similarly, for the subject matter of the Examiner's Groups VII-XII. In the event the Examiner rejoins these Groups, the Examiner is requested to issue a further restriction requirement which allows the applicants a further opportunity to elect from the newly constituted requirement.

The Examiner alleged that the inventions are distinct, each from each other because the subject matter of the Examiner's Groups I-VI and VII-XII are drawn to completely different chemical compounds that are patentably distinct. The Examiner also alleges that each of the inventions I-VI are different structural compounds as are the subject matter of Groups VI-XII, and are therefore patentably distinct.

The Examiner further asserts that the subject matter of the Examiner's Groups I-VI and XIII are related as product and process of use. The Examiner states that the subject matter can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). The Examiner stated that in the instant case the product as claimed can be used in a materially different process such as for its enzymatic activity not related to the method of group XIII. The Examiner stated that group XIII is not related to the subject matter of Groups I-VI, as claimed.

Alleging these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and divergent subject matter, the Examiner asserted that restriction for examination purposes as indicated is proper. The applicants respectfully disagree and note the Examiner has admitted that the subject matter of many of the indicated Groups has not been separately classified. Withdrawal of the restriction requirement therefor is requested.

The applicants further submit that more than just one uricase enzyme sequence should be examined. More specifically, applicants request that all six uricase enzyme

sequences recited in claim 5 be examined. Applicants make this request based on the practice the Patent Office has adopted with respect to nucleotide sequences as stated in M.P.E.P. § 803.04. Specifically, according to M.P.E.P. § 803.04, a "reasonable number" of sequences should be examined in one application. Applicants respectfully submit that six constitutes a reasonable number and should fall within the limits of Patent Office practice.

With respect to the restriction requirement, applicants respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 USC 121, restriction may be required if two or more independent and distinct inventions are claimed in one application. Under M.P.E.P. § 803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. That is, there are two criteria for a proper requirement for restriction: 1) the invention must be independent and distinct, **and** 2) there must be a serious burden on the Examiner if restriction is not required.

Applicants respectfully point out that the Examiner has indicated that a search of Groups I-VI would require a search of the exact same class and sub-class within the Patent Office classification system. In view of this, together with the fact that the application contains only a small and finite number of amino acid sequences, applicants respectfully submit that there would not be a serious burden on the Examiner if restriction to a single species of amino acid sequence is not required.

Furthermore, the Groups composed of the subject matter of the Examiner's Groups I-VI and VII-XII are not independent each from the other as alleged by the Examiner. The subject matter of the Examiner's Groups I-VI are directed to uricase enzymes and the subject matter of the Examiner's Groups VII-XII are directed to nucleic acid molecules encoding such uricase enzymes, vectors and host cells.

Under M.P.E.P. § 802.01, "independent" means there is no disclosed relationship between the subjects disclosed. Since amino acid sequences are by definition, dependent on the nucleic acid sequences which encode them, applicants submit that the subject matter of the Examiner's Groups I-VI and VII-XII are not independent, and that restriction to either of these Groups is not proper. The Examiner is requested to

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appreciate in this regard that the present application is a 371 of PCT/US99/17678 such that the principles of unity of invention apply in considering issues of restriction. See, MPEP § 1893.03(d) and Example 17 of Annex B of the PCT Administrative Instructions, copies attached.

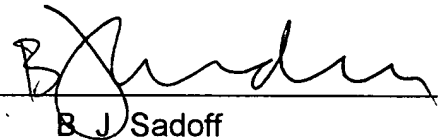
In view of the foregoing, applicants maintain that requirement for restriction between Groups I-VI and VII-XII is not proper under 35 USC 121 and respectfully request that the Examiner reconsider and withdraw the requirement for restriction. The restriction requirement is not properly based as the present application is a 371 application and a new Office Action is requested, which follows the principles of unity of invention, in the event the Examiner continues to believe restriction is required.

An early and favorable Action on the merits of all the claimed subject matter is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____



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